SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the U.S. market:	U.S. access to the EC market:
The names and scope of responsibilities of Conformity Assessment Bodies located in the EC and listed in accordance with this Sectoral Annex: (to be provided by the EC)	The names and scope of responsibilities of Conformity Assessment Bodies located in the U.S. and listed in accordance with this Sectoral Annex: (to be provided by the U.S.)

SECTION VI

DESIGNATING, LISTING, SUSPENDING AND WITHDRAWING CONFORMITY ASSESSMENT BODIES

EC access to the U.S. market:	U.S. access to the EC market:
Conformity assessment bodies from the EC shall be designated by the EC Authorities identified in Section IV and recognized by the Joint Committee, in accordance with the recognition procedures in the Agreement and this Annex.	Conformity assessment bodies from the U.S. shall be designated by the U.S. Authority identified in Section IV and recognized by the Joint Committee, in accordance with the recognition procedures in the Agreement and Council Directive 73/23/EEC.
Conformance with the appropriate ISO/IEC Guides or the corresponding EN 45000 series of standards shall be deemed consistent with U.S. requirements identified in Section I.	Conformance with the appropriate EN-45000 series of standards or the corresponding ISO/IEC Guides shall be deemed consistent with the requirements of Council Directive 73/23/EEC.
For purposes of designation and listing, EC Designating Authorities identified in Section IV shall designate conformity assessment bodies located in the EC by filing a properly prepared proposal for listing, which includes a complete lab assessment under the U.S. OSHA procedures. OSHA shall notify the EC Designating Authority normally within 30 days as to whether the proposal is complete or whether additional information is required.	For purposes of designating and listing, the U.S. Designating Authority identified in Section IV shall designate conformity assessment bodies located in the U.S. by filing a properly prepared proposal for listing with the EC, which includes a complete lab assessment under the following EC or Member State procedures, as appropriate.
OSHA shall rely on the EC Designating Authorities identified in Section IV for conducting on-site reviews at the respective Member States' conformity assessment bodies.	The EC shall notify the U.S. Designating Authority within 30 days as to whether the proposal is complete and shall indicate, where applicable, any additional information that is required.

SECTION VI (continued)

Upon receipt of a complete proposal, the U.S. exercising its authority under its law shall: (a) prior to the passage from the transitional phase into the operational phase in the Telecommunication Equipment and Electromagnetic Compatibility (EMC) Sectoral Annexes, give notice of its consent or objection to a proposed conformity assessment body to the Joint Committee. The listing of an agreed conformity assessment body in Section V of this Sectoral Annex shall only occur upon such passage from the transitional phase into the operational phase of those Sectoral Annexes; (b) subsequent to passage from the transitional phase into the operational phase in the Telecommunication Equipment and Electromagnetic Compatibility (EMC) Sectoral Annexes, give notice of its consent or objection to a proposed conformity assessment body to the Joint Committee normally within 120 business days. The listing of an agreed conformity assessment body in Section V of this Sectoral Annex shall occur upon notice of consent to the Joint Committee and the Joint Committee's decision to list such body. These listing procedures shall supersede the procedures in Article 7(c) of the Agreement in its entirety and the time periods set out in Article 7(d) of the Agreement.	Upon receipt of a complete proposal, the EC shall give notice of consent or objection to the Joint Committee within 60 days. The Joint Committee shall monitor the recognition of conformity assessment bodies and confirm such a recognition by listing them in Section V of this Sectoral Annex.
EC conformity assessment bodies listed in Section V shall have NRTL status in the U.S.	The U.S. conformity assessment bodies listed in Section V shall have Notified Body status within the EC.

SECTION VI (continued)

With regard to the suspension of a conformity assessment body listed in this Sectoral Annex, the period specified in Article 8(e) of the Agreement shall begin to run after a Party has notified the Joint Sectoral Committee or the Joint Committee, pursuant to Article 8(c) of the Agreement, that it proposes to revoke the conformity assessment body's recognition in accordance with its procedures under its applicable domestic law. Except as provided for in this Section, procedures for designation, listing, suspension and withdrawal of conformity assessment bodies under this Sectoral Annex shall be carried out in accordance with Articles 7, 8 and 9 of the Agreement.	

SECTION VII

JOINT SECTORAL COMMITTEE FOR ELECTRICAL SAFETY

1. The Joint Sectoral Committee for Electrical Safety (JSC/ES) consists of representatives of the U.S. and the EC. OSHA shall represent the U.S. on this Joint Sectoral Committee. The EC and OSHA may invite the participation of others as deemed necessary. Each Party shall have one vote and decisions shall be made by unanimous consent, unless otherwise specified herein. The Joint Sectoral Committee shall determine its own rules of procedure.

2. The Joint Sectoral Committee may address any matter related to the effective functioning of this Sectoral Annex, including:

   - developing improved procedures and criteria for designation in order to facilitate the assessment and preparation of proposals by Designating Authorities, with a view towards expediting the period between designation and listing;

   - providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral Annex;

   - advising the Parties on matters relating to this Sectoral Annex; and

   - enhancing the operation of this Sectoral Annex.

SECTORAL ANNEX

FOR

RECREATIONAL CRAFT

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

The purpose of this Sectoral Annex is to establish a framework to accept certificates of conformity issued in the territory of one Party in accordance with the regulatory requirements of the other Party as referenced in this Sectoral Annex.

To facilitate that purpose, a transitional period of 18 months is arranged to build confidence as defined in this Sectoral Annex, Section VI.

SECTION I
LEGISLATIVE, REGULATORY, AND ADMINISTRATIVE REQUIREMENTS

1. For the European Community:

   Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to recreational craft.

2. For the U.S.:

   46 U.S.C. Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.

SECTION II
SCOPE AND COVERAGE

1. This Sectoral Annex applies to all recreational craft which in the European Community or the United States are subject to conformity assessment by a conformity assessment body or an approval procedure, as applicable, before being put on the market.

2. The product coverage for each Party shall be determined by the following relevant requirements:

   (a) for the European Community:
   Recreational craft as defined in Directive 94/25/EC.

   (b) for the United States:
   Any product falling under the scope of 46 U.S.C. Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.

3. The Parties agree that for mutual recognition to operate under this Sectoral Annex, the following arrangements shall apply:

   (a) for approvals to European Community requirements, conformity assessment bodies designated by the U.S. shall establish compliance as required to be demonstrated by Directive 94/25/EC. This demonstration of compliance shall be recognized in the European Community and products so certified shall have unrestricted access to the EC market for sale as recreational craft, pursuant to Section I;

   (b) for approvals to United States requirements, conformity assessment bodies designated by the European Community shall establish compliance as required to be demonstrated as set forth in paragraph 2(b) of this Section and products so certified shall have unrestricted access to the U.S. market for sale as recreational craft, pursuant to Section I.

SECTION III
AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES

EC access to the U.S. market:	U.S. access to the EC market:
- Belgium Ministère des Communications et de l'infrastructure Ministerie van Verkeer en Infrastructuur - Germany Bundesministerium für Wirtschaft - Spain for telecommunication equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energía - France Ministère de l'Equipment, des Transports et du Logement - Italy Ministero dell'Industria, del Commercio e dell' Artigianato - Netherlands De Minister van Verkeer en Waterstaat - Finland Merenkulkuhallitus/sjöfartsstyrelsen - Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) - UK Department of Trade and Industry	National Institute for Standards and Technology (NIST)

SECTION IV
DESIGNATING, LISTING, SUSPENDING AND WITHDRAWING CONFORMITY ASSESSMENT BODIES

1. For the purpose of this Sectoral Annex, each Party shall designate competent conformity assessment bodies to carry out conformity assessment and approval to the requirements of the other Party. Such designation shall be carried out according to the procedures set out in Article 7 of the Agreement. A list of conformity assessment bodies together with the products and procedures for which they have been listed, is set out in Section V below.

2. Each Party agrees that the listed conformity assessment bodies comply with the requirements for such bodies established by the other Party. These are:

   (a) for the European Community, bodies which are Notified Bodies in accordance with Directive 94/25/EC, are deemed to be in compliance with U.S. requirements;

   (b) for the U.S., in accordance with the requirements set out in the regulations listed in Section I, the conformity assessment bodies listed in Section V are designated by NIST using the evaluation procedures contained in the appropriate EN-45000 series of standards or the corresponding ISO/IEC Guides.

3. With regard to the designation, listing, suspension and withdrawal of conformity assessment bodies under this Sectoral Annex, the specific procedures in Articles 7, 8 and 9 of the Agreement shall be followed.

SECTION V

CONFORMITY ASSESSMENT BODIES

EC access to the U.S. market:	U.S. access to the EC market:
The names and scope of responsibilities of Conformity Assessment Bodies located in the EC and listed in accordance with this Sectoral Annex: (to be provided by EC)	The names and scope of responsibilities of Conformity Assessment Bodies located in the U.S. and listed in accordance with this Sectoral Annex: (to be provided by the US)

SECTION VI

TRANSITIONAL ARRANGEMENT

1. There shall be a transitional period of 18 months prior to the operations of this Sectoral Annex.

2. The purpose of the transitional arrangement is to provide a means whereby the Parties to this Agreement can cooperate to establish a system for designating conformity assessment bodies and can mutually build confidence in the abilities of these bodies. Successful completion of this transitional arrangement is intended to result in a determination that conformity assessment bodies comply with the applicable criteria and to have the equipment approved by the conformity assessment bodies of the exporting country accepted by the approval authority of the importing country.

3. During this transitional period, the parties shall:

   (a) exchange information on technical data and conformity assessment criteria and procedures, thus developing greater familiarity with their respective regulatory requirements; and

   (b) carry out or recommend any applicable policy, legislative and regulatory changes necessary for the provisions of this Annex.

4. Product Scope

   All products covered by Section II of this Annex.

5. Cooperation

During this transitional period, both Parties shall endeavour to jointly sponsor seminars for the purpose of improving the understanding of technical specifications applicable in each Party's jurisdiction.

6. Inspections

Inspections or audits shall be permitted to verify compliance of conformity assessment bodies with their responsibilities under this Agreement. The scope of these inspections or audits shall be agreed upon in advance by both Parties.

SECTION VII

ADDITIONAL PROVISIONS

1. In accordance with the relevant provisions of the Agreement, the Parties shall ensure the continued availability of the names of their respective notified bodies or conformity assessment bodies, and shall regularly supply details of certifications issued in order to facilitate post market surveillance.

2. The Parties note that, to the extent that requirements for electrical safety or electromagnetic compatibility may apply to products covered by this Sectoral Annex, the provisions of the Sectoral Annexes on Electrical Safety and Electromagnetic Compatibility apply.

SECTION VIII

DEFINITIONS

Notified Body means a third party authorized to perform the conformity assessment tasks specified in Directive 94/25/EC, which has been appointed by a Member State from the bodies falling within its jurisdiction. The Notified Body has the necessary qualifications to meet requirements laid down in Directive 94/25/EC and has been notified to the Commission and to the other Member States.

SECTORAL ANNEX
FOR
PHARMACEUTICAL GOOD MANUFACTURING PRACTICES
(GMPs)

U.S. - EC MRA Pharmaceutical Good Manufacturing Practices Annex

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

U.S. - EC MRA Pharmaceutical Good Manufacturing Practices Annex

CHAPTER 1

DEFINITIONS, PURPOSE, SCOPE AND COVERAGE

Article 1

Definitions

1. "Equivalence" of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. "Equivalence" does not require that the respective regulatory systems have identical procedures.

2. "Enforcement" means action taken by an authority to protect the public from products of suspect quality, safety and efficacy or to assure that products are manufactured in compliance with appropriate laws, regulations, standards and commitments made as part of the approval to market a product.

3. "Good Manufacturing Practices" (GMPs): (The U.S. and EC have agreed to revisit these concepts)

   GMPs mean the requirements found in the respective legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

   GMPs are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this Annex, GMPs include therefore the system whereby the manufacturer receives the specifications of

the product and/or process from the Marketing Authorization/Product Authorization or License holder or applicant and ensures the product is made in compliance with its specifications (Qualified Person certification in the EC).

4. "Inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practices and/or commitments made as part of the approval to market a product.

5. "Inspection Report" means the written observations and Good Manufacturing Practices compliance assessment completed by an authority listed in Appendix 2.

6. "Regulatory System" means the body of legal requirements for Good Manufacturing Practices, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

Article 2

Purpose

The provisions of this Annex govern the exchange between the Parties and normal endorsement by the receiving authority of official Good Manufacturing Practices (GMPs) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the Parties, which is the cornerstone of this Annex.

Article 3

Scope

The provisions of this Annex shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community before products are

marketed (hereafter referred to as "pre-approval inspections") as well as during their marketing (hereafter referred to as "post-approval inspections").

Appendix 1 names the laws, regulations and administrative provisions governing these inspections and the GMPs requirements.

Appendix 2 lists the authorities participating in activities under this Annex.

Articles 6, 7, 8, 9, 10 and 11 of the Agreement do not apply to this Annex.

Article 4

Product coverage

These provisions will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the EC) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both Parties as listed in Appendix 2.

Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Annex. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals and medicinal gases are also excluded during the transition phase, their situation will be reconsidered at the end of the transition period. Products regulated by the Center for Biologics Evaluation and Research as devices are not covered under this Annex.

Appendix 3 contains an indicative list of products covered by this Annex.

CHAPTER 2

TRANSITION PERIOD

Article 5

Length of transition period

A three-year transition period will start immediately after the effective date of the Agreement.

Article 6

Equivalence assessment

1. The criteria to be used by the Parties to assess equivalence are listed in Appendix 4. Information pertaining to the criteria under Community competence will be provided by the Community.

2. The authorities of the parties will establish and communicate to each other their draft programmes for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programmes will be carried out, as deemed necessary by the authorities, for post- and pre-approval inspections and for various product classes or processes.

3. The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the Parties will ensure that efforts are made to save resources.

4. Equivalence assessment for authorities added to Appendix 2 after the effective date of this agreement will be conducted as described in this Annex, as soon as practicable.

Article 7

Participation in the equivalence assessment and determination

The authorities listed in Appendix 2 will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

Article 8

Other transition activities

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

CHAPTER 3

END OF TRANSITION PERIOD

Article 9

Equivalence determination

Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix 4, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g. post-approval or pre-approval) or product classes or processes.

The Parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of non-equivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

Article 10

Authorities not listed as currently equivalent

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

CHAPTER 4

OPERATIONAL PERIOD

Article 11

Start of the operational period

The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in Article 12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the Parties will agree on procedures for exercising this option.

In the EC, the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

Article 12

Nature of recognition of inspection reports

Inspection reports (containing information as established under Article 8), including a GMP compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing Party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing Party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing Party may request clarification from the authority of the exporting Party which may lead to a request for re-inspection. The authorities will endeavour to respond to requests for clarification in a timely manner.

Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

Article 13

Transmission of post-approval inspection reports

Post-approval GMP inspection reports concerning products covered by this Annex will be transmitted to the authority of the importing country within 60 calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90 calendar days of the request.

Article 14

Transmission of pre-approval inspection reports

A preliminary notification that an inspection may have to take place will be made as soon as possible.

Within 15 calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the EC, requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

Reports of pre-approval inspections will be sent within 45 calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

Article 15

Monitoring continued equivalence

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections and the conduct of common training sessions.

Article 16

Suspension

Each Party has the right to contest the equivalence of an authority. This right will be exercised in an objective and reasoned manner in writing to the other Party.
The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the JSC determines that verification of equivalence is required, it may be carried out jointly by the Parties in a timely manner, pursuant to Article 6.